Valocordin® tablets

translated from original Russian leaflet by RussianMeds Store
https://russianmeds.com

Name in Cyrillic: ВАЛОКОРДИН®

Active substances: Phenobarbital + Ethylbromisovalerinate

Pharmachologic effect: sedative

Pharmacodynamics:
Valocordin is a combined drug, acting due to the pharmacological properties of the components that make up its composition. It has a sedative and antispasmodic effect.
Phenobarbital has a sedative (in low doses), hypnotic, muscle relaxant and antispasmodic effect. It helps to reduce the excitation of the central nervous system and facilitates the onset of sleep, enhances the sedative effect of another active substance.
Ethylbromisovalerianate has a sedative (similar to the effect of valerian) and antispasmodic effect mainly of receptors in the oral cavity and nasopharynx, caused by irritation, a decrease in reflex excitability in the central parts of the nervous system and increased inhibition in neurons of the cortex and subcortical structures of the brain, as well as a decrease in the activity of local vasomotor centers and direct antispasmodic effect on smooth muscles.

Pharmacokinetics:
When taken orally, phenobarbital is absorbed slowly, completely. Cmax in blood plasma is determined after 1-2 hours, the connection with plasma proteins - 50%, in newborns - 30-40%. It is metabolized in the liver, induces microsomal liver enzymes - isoenzymes CYP3A4, CYP3A5, CYP3A7 (the rate of enzymatic reactions increases 10-12 times). It accumulates in the body. The half-life is 2-4 days. It is excreted by the kidneys in the form of glucuronide, about 25% - unchanged. Phenobarbital penetrates into breast milk and through the placental barrier.
There are no data on the pharmacokinetics of ethylbromisovalerianate.

Indications:
Valocordin is indicated for use as a symptomatic sedative in functional disorders of the CVS, neurosis-like conditions, accompanied by increased irritability, sleep disturbance, tachycardia, a state of excitement with pronounced vegetative manifestations.

Contraindications:
hypersensitivity to the components of the drug;
acute hepatic porphyria;
hereditary lactose intolerance;
glucose-galactose malabsorption;
severe impairment of kidney and / or liver function;
pregnancy;
breastfeeding period;
age up to 18 years (efficacy and safety have not been established).

Use with caution:
impaired renal function;
impaired liver function;
simultaneous use with drugs that are metabolized in the liver (see "Interaction").

Pregnancy and breast-feeding:
The use of the drug during pregnancy and during breastfeeding is contraindicated, because phenobarbital passes the

placenta and has a teratogenic effect, has a negative effect on the formation and further functioning of the central nervous system of the fetus and newborn.
Phenobarbital passes into breast milk. The development of physical dependence in newborns is possible.
If it is necessary to use the drug during lactation, breastfeeding should be discontinued.

Side effects:
Drowsiness, dizziness, slow heart rate, decreased ability to concentrate, allergic reactions. Gastrointestinal disturbances may occur.
These phenomena disappear with a decrease in the dose of the drug. With prolonged use of the drug, it is possible to develop drug dependence, addiction, withdrawal syndrome, as well as the accumulation of bromine in the body and the development of bromism (depressed mood, apathy, rhinitis, conjunctivitis, hemorrhagic diathesis, impaired coordination of movements).
Very rarely, hypersensitivity reactions may occur (shortness of breath, Quincke's edema, severe unwanted skin reactions).
There have been reports of decreased bone mineral density, the development of osteopenia and osteoporosis, and fractures in patients taking phenobarbital for a long time.
The mechanism of the effect of phenobarbital on bone metabolism has not been identified.
If the patient has side effects indicated in the instructions, or they are aggravated, or any other side effects that are not indicated in the instructions are noticed, it is necessary to inform the doctor about this.

Interaction:
Medicines that depress the central nervous system, enhance the effect of the Valocordin.
Ethanol enhances the effect of the Valocordin.
Phenobarbital (an inducer of microsomal oxidation) can reduce the effectiveness of drugs metabolized in the liver (including derivatives of coumarin, lamotrigine, thyroid hormones, doxycycline, chloramphenicol, antifungal drugs (azole type), antibiotics, sulfonamides, griseofulvin, corticosteroids and oral contraceptives) ...
Valocordin may increase the toxicity of methotrexate.
The effect of the Valocordin is enhanced by the use of valproic acid.
If the patient is using the above or other drugs (including over-the-counter), consult a doctor before using Valocordin®.

Dosing and Administration:
Valocordin should be taken before meals with a sufficient amount of water. Adults take 1-2 tablets 2 times a day. With tachycardia, a single dose can be increased to 3 tablets.
The maximum daily dose is 6 tablets.
The dosage and duration of use of the drug is set by the doctor individually for each patient.

Overdose:
Symptoms: CNS depression, nystagmus, ataxia, decreased blood pressure, agitation, dizziness, weakness, chronic bromine intoxication (depression, apathy, rhinitis, conjunctivitis, hemorrhagic diathesis, impaired coordination of movements).
In severe cases - coma, accompanied by tissue hypoxia, respiratory failure, tachycardia, arrhythmia, vascular collapse, decreased peripheral reflexes.

Treatment: discontinuation of the drug, gastric lavage and symptomatic therapy. With depression of the central nervous system - caffeine, niketamide.

There is no specific antidote.

Special instructions:
There is no experience of using Valocordin in children under 18 years of age.
With uncontrolled use of Valocordin, drug dependence may occur.
You should not drink alcohol while taking Valocordin.

When using Valocordin you should avoid potentially hazardous activities that require an increased concentration of attention and speed of psychomotor reactions (including driving, working with driving mechanisms).

Manufacturer: Manufactured in Russia by Krewel Meuselbach

Reliable supplier with fast Worldwide shipping:
RussianMeds Online Store
https://russianmeds.com

Storage:
The temperature is not above 25 °C (77 °F)
Keep out of the reach of children.
Shelf-life of the drug is 3 years.